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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,218	02/25/2002	Shiro Shibayama	Q68658	4504

7590 05/11/2004

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT PAPER NUMBER

1646

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/081,218	SHIBAYAMA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3-7 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-7 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 08/439,457.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 2, 8-10 have been canceled on 2/25/2002. Amended claims 3-7, and new claims 11-15 are pending and under consideration in the instant application.

#### ***Specification***

1. In the first line of the instant specification, Applicants are requested to update the status of the prior applications to which the instant application is claiming benefit. The status of nonprovisional parents 09/246,355, 08/852,811 and 08/439,457 should be updated and the expression, "now, abandoned" should follow the filing date of the parent applications.

#### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 7, 13, 15, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims embrace a host cell in the body of a transgenic animal, or a host cell in a gene therapy patient. The claims encompasses human cells, fetuses and embryos, as well as non-human cells including animals, vertebrates, mammals, primates, chimeric animals, germ cells (including oocytes and sperm), fertilized eggs, fetal tissues and organs. However, since it would that Applicants do not intend to claim such human cells, amending the claims to require non-human host cells and the hand-of-man would obviate this rejection i.e. an isolated non-human mammalian host cell.

#### ***Claim rejections-35 U.S.C. 101/112, first paragraph***

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4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-7 and 11-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The instant claims are drawn to a polynucleotide encoding a polypeptide, which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as a membrane protein because the polypeptide has the character of an adhesion molecule because it includes a lot of Ser, Thr and Pro (page 3, third full paragraph), the instant invention is incomplete. The specification discloses that the claimed polynucleotide encodes a novel factors generated in endothelial cells (page 2, third full paragraph). The specification discloses that the translation product of the polynucleotide of SEQ ID NO:2 has a lot of Ser, Thr and Pro (page 3, third full paragraph), however, the instant specification does not disclose any information regarding functional characteristics or the biological activity of the protein encoded by the polynucleotide. While the specification on page 3, second paragraph describes the instant protein as a novel membrane protein, there is no guidance given about which specific activity/activities the polypeptide encoded by the claimed polynucleotide would be likely to have.

There has to be physiological significance for the polypeptide disclosed in the specification. This requirement is analogous to basic scientific characterization, however, in the instant case no substantial benefit for the claimed polynucleotide encoding a protein of SEQ ID

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NO:2, is currently disclosed, but an exploratory significance. Therefore, Applicants have failed to disclose a substantial or specific utility for the polynucleotide encoding a protein of SEQ ID NO:2. The specification does not demonstrate that the polypeptide encoded by the claimed polynucleotide actually displays any activities. In the absence of knowledge of the specific biological significance of the protein encoded by the claimed polynucleotide, there is no immediately obvious patentable use for it. Since the instant specification does not disclose a "real world" use for the polynucleotide encoding the protein of SEQ ID NO:2, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

A protein of unknown function would have utility if it can be employed as an indicator of a diseased state or of the presence of a disorder. The only disclosed property for the protein of the instant invention is that it is a membrane protein in endothelial cells (see page 3, second para, last 2 lines). Applicant is only required to identify one substantial credible utility and the employment of this protein only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. § 101 because the courts have interpreted this statute as requiring an invention to have "substantial utility" "where specific benefit exists in currently available form". The employment of a protein of the instant invention, as a marker for ovarian cancer is not a substantial or specific utility.

The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign

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function to a protein. Therefore, there is little doubt that, after further characterization, the protein is found to be member of the adhesion molecule family of proteins, the protein of SEQ ID NO: 2, would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well-established utility. The claimed invention is directed to a polypeptide of as yet undetermined function or biological significance. Thus, since there is no biological activity disclosed for the protein encoded by the claimed nucleic acid, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

Claims 3-7, and 11-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose a biological activity for the claimed polynucleotide encoding a protein of SEQ ID NO:2, therefore, there is no specific and substantial asserted utility or well established for the claimed protein. The fact that the claimed nucleic acid encodes a protein that has the character of an adhesion molecule because it includes a lot of Ser, Thr and Pro is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

***Conclusion***

No claim is allowable.

***Advisory Information***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

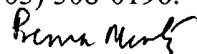
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
March 8, 2004